

510(K) SUMMARY**A. Submitter Information****JUN 13 2014**

Manufacturer: Medos International Sàrl
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Submitter: DePuy Synthes Spine
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B. Date Prepared June 12, 2014

C. Device Name

Device Name	Regulation Number	Product Code
BENGAL® System	888.3060, (888.3080)	MQP, (MAX, ODP)
BENGAL® Stackable System	888.3060, (888.3080)	MQP, (MAX)
DEVEX® System	888.3060, (888.3080)	MQP, (MAX)
OCELOT® Stackable Cage System	888.3060	MQP
CONCORDE® Bullet Lumbar Interbody System	888.3060, (888.3080)	MQP, (MAX)
COUGAR® System	888.3060, (888.3080)	MQP, (MAX)
LEOPARD® System	888.3060, (888.3080)	MQP, (MAX)
Device Name	Regulation Number	Product Code
CONCORDE® Inline Lumbar Interbody System	888.3080	MAX
COUGAR® LS Lateral Cage System	888.3080	MAX

Common/Usual Name: Spinal Intervertebral Body Fixation Orthosis (VBR);
Intervertebral Body Fusion Device (IBF)

Classification Name: Spinal Intervertebral Body Fixation Orthosis
Per 21 CFR 888.3060
Intervertebral Body Fusion Device
Per 21 CFR 888.3080

D. Predicate Device Name

Trade name:

- BENGAL® System
- BENGAL® Stackable System
- CONCORDE® Bullet Lumbar Interbody System
- CONCORDE® Inline Lumbar Interbody System
- COUGAR® System
- COUGAR® LS Lateral Cage System
- DEVEX® System
- LEOPARD® System
- OCELOT® Stackable Cage System

E. Device Name and Description

BENGAL® System: The BENGAL® System is a carbon fiber reinforced polymer (CFRP) interbody fusion and VBR device. The cage distracts and maintains the intervertebral height, as well as providing restoration of cervical lordosis. The range of cages available is based on natural anatomical variation.

BENGAL® Stackable System: The Bengal® Stackable System is a radiolucent, multilevel corpectomy solution that provides a system approach to restoring natural lordosis. The BENGAL® Stackable Cage System offers versatility in footprint options (3 are available), height options (18 to 66 mm in 2-mm increments), and lordotic angle options. The stackable cages (LRG and XLG) are held together by a titanium locking screw and nut. The titanium locking screw is used for all stackable constructs.

CONCORDE® Bullet Lumbar Interbody System: The CONCORDE Bullet implants, manufactured from Carbon Fiber Reinforced Polymer (CFRP), are interbody cages designed with a bullet nose for ease of insertion into the interbody space. The CONCORDE Bullet offers optimized area for bone graft and tantalum markers.

CONCORDE® Inline Lumbar Interbody System: The CONCORDE® Inline Lumbar Interbody System completes the offering within the CONCORDE® family of products with an implant designed to facilitate ease of posterior insertion and improve resistance to migration. The CONCORDE Inline is designed with a bullet nose for ease of insertion into the interbody space and are manufactured from Carbon Fiber Reinforced Polymer (CFRP).

COUGAR® System: The COUGAR® System is an Anterior Spinal Implant System manufactured of Carbon Fiber Reinforced Polymer (CFRP). COUGAR® is available in three footprints - Small, Medium and Large and varying heights from 10-20mm. COUGAR® incorporates an anatomic design with 5, 10, 15, and 20 degrees of lordosis. The cages offer tantalum marker beads for radiographic location and orientation of the implant.

COUGAR® LS Lateral Cage System: The COUGAR® LS Lateral Cage System The COUGAR® LS Lateral Cage System consists of the PEEK/carbon fiber composite cages (CFRP). Cages are available in parallel or lordotic configurations and are available in various sizes to match

patient anatomy. The cage structure is radiolucent with tantalum x-ray wire so that healing can be assessed by normal radiographic methods. The cages have teeth that resist rotation and migration and have cavities to accept packing of autogenous bone graft. The implants may be utilized in either an open or minimally invasive surgical approach. The implants are placed using a lateral surgical approach.

DEVEX® System: The DEVEX® System is indicated for use in the thoracolumbar spine (i.e., T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The DEVEX® System is also indicated for treating fractures of the thoracic and lumbar spine. The DEVEX® System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period.

LEOPARD® System: The LEOPARD® System is made of carbon fiber reinforced polymer (CFRP) material that has a modulus of elasticity approximating that of cortical bone. The LEOPARD® System meets the structural requirements of anterior column support while optimizing the fusion environment through an open, load-sharing design.

OCELOT® Stackable Cage System: The OCELOT® Stackable Cage System provides anterior column support for single or multi-level corpectomies or total vertebrectomies from T1 to L5. The system consists of one or more PEEK™ Carbon Fiber Polymer cages that are stacked to a desired height, accommodating various patient needs. The PEEK™ Carbon Fiber Reinforced Polymer material emulates the biomechanical properties of human cortical bone, optimizing the likelihood of a sound arthrodesis.

F. Intended Use

BENGAL® System:

This system was cleared in K081917 (VBR & IBF) on May 22, 2009. Intended Use listed respectively.

K081917

CONCORDE, COUGAR, DEVEX, and LEOPARD Systems Indications.

The CONCORDE, COUGAR, DEVEX, and LEOPARD Systems are indicated for use as intervertebral body fusion devices in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine L2-S1). Patients should have six months of non-operative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine and are placed via either a PLIF (CONCORDE), TLIF (CONCORDE, DEVEX, LEOPARD) or anterior (COUGAR) approach using autogenous bone. When used as interbody fusion devices these implants are intended for use with DePuy Spine supplemental internal fixation.

The CONCORDE, COUGAR, DEVEX, and LEOPARD Systems are indicated for use in the thoracolumbar spine (i.e., T1-L5) to replace a diseased vertebral body resected or excised

for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. These systems are also indicated for treating fractures of the thoracic and lumbar spine. These systems are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. When used as a vertebral body replacement device these systems are intended for use with DePuy Spine supplemental internal fixation.

BENGAL System Indications

The BENGAL System is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one level of the cervical spine with accompanying radicular symptoms. Patients should have six weeks of non-operative treatment prior to surgery. BENGAL implants are used to facilitate fusion in the cervical spine (C2-T1) and are placed via an anterior approach using autogenous bone. When used as an interbody fusion device, DePuy Spine supplemental fixation should be used.

The BENGAL System is indicated for use in the thoracolumbar spine (i.e., T1-L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. This system is also indicated for treating fractures of the thoracic and lumbar spine. This system is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. When used as a vertebral body replacement device this system is intended for use with DePuy Spine supplemental internal fixation.

BENGAL® Stackable System:

510(k) submission K073649 cleared January 25, 2008.

K073649

The VBR Spinal System is indicated for use in the thoracolumbar spine (i.e., T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body.

The VBR Spinal Systems are also indicated for treating fractures of the thoracic and lumbar spine.

The VBR Spinal Systems are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period.

The VBR Spinal System is intended for use with supplemental internal fixation. The supplemental internal fixation systems that may be used include titanium plate or rod systems (i.e., KANEDATM SR, UNIVERSITY PLATETM, M-2 ANTERIOR PLATETM, ISOLA®, VSPC, MOSS® MIAMI, TIMX TM, MONARCH TM, EXPEDIUM TM, VIPER TM, and PROFILE TM).

CONCORDE® Bullet Lumbar Interbody System:

Original 510(k) submission K052746 (VBR) cleared October 21, 2005; subsequent K081917 (VBR & IBF) cleared May 22, 2009. Intended Use listed respectively.

K052746

The Concorde VBR Spinal System is indicated for use in the thoracolumbar spine (i.e., T1-L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body.

The Concorde VBR Spinal System is also indicated for treating fractures of the thoracic and lumbar spine.

The Concorde VBR Spinal System is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period.

The Concorde VBR Spinal System is intended for use with supplemental internal fixation. The supplemental internal fixation systems that may be used with the Concorde VBR Spinal System include DePuy Spine titanium plate or rod systems (i.e., Kaneda SR, University Plate, M-2, ISOLA, VSP, Moss Miami, T MX, MONARCH, Expedium, Viper, and Profile).

K081917

CONCORDE, COUGAR, DEVEX, and LEOPARD Systems Indications.

The CONCORDE, COUGAR, DEVEX, and LEOPARD Systems are indicated for use as intervertebral body fusion devices in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1). Patients should have six months of non-operative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine and are placed via either a PLIF (CONCORDE), TLIF (CONCORDE, DEVEX, LEOPARD) or anterior (COUGAR) approach using autogenous bone. When used as interbody fusion devices these implants are intended for use with DePuy Spine supplemental internal fixation.

The CONCORDE, COUGAR, DEVEX, and LEOPARD Systems are indicated for use in the thoracolumbar spine (i.e., T1-L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. These systems are also indicated for treating fractures of the thoracic and lumbar spine. These systems are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. When used as a vertebral body replacement device these systems are intended for use with DePuy Spine supplemental internal fixation.

BENGAL System Indications The BENGAL System is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one level of the cervical spine with accompanying radicular symptoms. Patients should have six weeks of non-operative treatment prior to surgery. BENGAL implants are used to facilitate fusion in the cervical spine (C2-T1) and are placed via

an anterior approach using autogenous bone. When used as an interbody fusion device, DePuy Spine supplemental fixation should be used.

The BENGAL System is indicated for use in the thoracolumbar spine (i.e., T1-L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. This system is also indicated for treating fractures of the thoracic and lumbar spine. This system is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. When used as a vertebral body replacement device this system is intended for use with DePuy Spine supplemental internal fixation.

CONCORDE® Inline Lumbar Interbody System:

510(k) submission K110694 cleared October 11, 2011.

K110694

The CONCORDE, CONCORDE Bullet, CONCORDE Curve, COUGAR, DEVEX, and LEOPARD Systems are indicated for use as intervertebral body fusion devices in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1). Patients should have six months of non-operative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine and are placed via either a PLIF (CONCORDE, CONCORDE Bullet), TLIF (CONCORDE, CONCORDE Bullet, CONCORDE Curve, DEVEX, LEOPARD) or anterior (COUGAR) approach using autogenous bone. When used as interbody fusion devices these implants are intended for use with DePuy Spine supplemental internal fixation products.

The CONCORDE, CONCORDE Bullet, CONCORDE Curve, COUGAR, DEVEX, and LEOPARD Systems are indicated for use in the thoracolumbar spine (i.e., T1-L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. These systems are also indicated for treating fractures of the thoracic and lumbar spine. These systems are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. When used as a vertebral body replacement device these systems are intended for use with DePuy Spine supplemental internal fixation products.

COUGAR® System:

Original 510(k) submission K030833 (VBR) cleared April 4, 2003; subsequent K081917 (VBR & IBF) cleared May 22, 2009. Intended Use listed respectively.

K030833

The DePuy AcroMed VBR System is indicated for use in the thoracolumbar spine (i.e., T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body.

The DePuy AcroMed VBR System is also indicated for treating fractures of the thoracic and lumbar spine.

The DePuy AcroMed VBR System is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period.

The DePuy AcroMed VBR System is intended for use with supplemental internal fixation. The supplemental internal fixation systems that may be used with the VBR System include DePuy AcroMed titanium plate or rod systems (i.e., Kaneda SR, University Plate, M-2, ISOLA, VSP, Moss Miami, TiMX, Monarch, and Profile).

K081917

CONCORDE, COUGAR, DEVEX, and LEOPARD Systems Indications.

The CONCORDE, COUGAR, DEVEX, and LEOPARD Systems are indicated for use as intervertebral body fusion devices in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1). Patients should have six months of non-operative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine and are placed via either a PLIF (CONCORDE), TLIF (CONCORDE, DEVEX, LEOPARD) or anterior (COUGAR) approach using autogenous bone. When used as interbody fusion devices these implants are intended for use with DePuy Spine supplemental internal fixation.

The CONCORDE, COUGAR, DEVEX, and LEOPARD Systems are indicated for use in the thoracolumbar spine (i.e., T1-L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. These systems are also indicated for treating fractures of the thoracic and lumbar spine. These systems are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. When used as a vertebral body replacement device these systems are intended for use with DePuy Spine supplemental internal fixation.

BENGAL System Indications The BENGAL System is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one level of the cervical spine with accompanying radicular symptoms. Patients should have six weeks of non-operative treatment prior to surgery. BENGAL implants are used to facilitate fusion in the cervical spine (C2-T1) and are placed via an anterior approach using autogenous bone. When used as an interbody fusion device, DePuy Spine supplemental fixation should be used.

The BENGAL System is indicated for use in the thoracolumbar spine (i.e., T1-L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a

collapsed vertebral body. This system is also indicated for treating fractures of the thoracic and lumbar spine. This system is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. When used as a vertebral body replacement device this system is intended for use with DePuy Spine supplemental internal fixation.

COUGAR® LS Lateral Cage System:

Original 510(k) submission K082128 cleared November 14, 2008; subsequent K110454 cleared May 13, 2011. Intended Use listed respectively.

K082128

The Lateral Cage System is indicated for intervertebral body fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive lateral approach. The Lateral Cage System is intended for use with DePuy Spine supplemental fixation.

K110454

The COUGAR LS Lateral Cage System is indicated for use in the thoracolumbar spine(i.e., T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. This system is also indicated for treating fractures of the thoracic and lumbar spine. The system is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. When used as a vertebral body replacement device, this system is intended for use with DePuy Spine supplemental internal fixation.

The COUGAR LS Lateral Cage System is also indicated for intervertebral body fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive lateral approach. When used as an interbody fusion device, this system is intended for use with DePuy Spine supplemental internal fixation.

DEVEX® System:

Original 510(k) submission K023835 (VBR) cleared January 29, 2003; subsequent K081917 (VBR & IBF) cleared May 22, 2009. Intended Use listed respectively.

K023835

The Devex Mesh System is indicated for use in the thoracolumbar spine (T1-L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve

anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body.

The Devex Mesh System is also indicated for treating fractures of the thoracic and lumbar spine.

The Devex Mesh System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period.

The Devex Mesh System is intended for use with supplemental internal fixation. The supplemental internal fixation systems that may be used with the Surgical Titanium Mesh System include DePuy AcroMed titanium plate or rod systems (e.g. Kaneda SR, University Plate, M-2, ISOLA, VSP, Moss Miami, TiMX, Monarch and Profile).

K081917

CONCORDE, COUGAR, DEVEX, and LEOPARD Systems Indications.

The CONCORDE, COUGAR, DEVEX, and LEOPARD Systems are indicated for use as intervertebral body fusion devices in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1). Patients should have six months of non-operative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine and are placed via either a PLIF (CONCORDE), TLIF (CONCORDE, DEVEX, LEOPARD) or anterior (COUGAR) approach using autogenous bone. When used as interbody fusion devices these implants are intended for use with DePuy Spine supplemental internal fixation.

The CONCORDE, COUGAR, DEVEX, and LEOPARD Systems are indicated for use in the thoracolumbar spine (i.e., T1-L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anteriordecompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. These systems are also indicated for treating fractures of the thoracic and lumbar spine. These systems are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. When used as a vertebral body replacement device these systems are intended for use with DePuy Spine supplemental internal fixation.

BENGAL System Indications The BENGAL System is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one level of the cervical spine with accompanying radicular symptoms. Patients should have six weeks of non-operative treatment prior to surgery. BENGAL implants are used to facilitate fusion in the cervical spine (C2-T1) and are placed via an anterior approach using autogenous bone. When used as an interbody fusion device, DePuy Spine supplemental fixation should be used.

The BENGAL System is indicated for use in the thoracolumbar spine (i.e., T1-L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve

anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. This system is also indicated for treating fractures of the thoracic and lumbar spine. This system is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. When used as a vertebral body replacement device this system is intended for use with DePuy Spine supplemental internal fixation.

LEOPARD® System:

This system was cleared in K081917 (VBR & IBF) on May 22, 2009. Intended Use listed respectively.

K081917

CONCORDE, COUGAR, DEVEX, and LEOPARD Systems Indications.

The CONCORDE, COUGAR, DEVEX, and LEOPARD Systems are indicated for use as intervertebral body fusion devices in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1). Patients should have six months of non-operative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine and are placed via either a PLIF (CONCORDE), TLIF (CONCORDE, DEVEX, LEOPARD) or anterior (COUGAR) approach using autogenous bone. When used as interbody fusion devices these implants are intended for use with DePuy Spine supplemental internal fixation.

The CONCORDE, COUGAR, DEVEX, and LEOPARD Systems are indicated for use in the thoracolumbar spine (i.e., T1-L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. These systems are also indicated for treating fractures of the thoracic and lumbar spine. These systems are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. When used as a vertebral body replacement device these systems are intended for use with DePuy Spine supplemental internal fixation.

BENGAL System Indications The BENGAL System is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one level of the cervical spine with accompanying radicular symptoms. Patients should have six weeks of non-operative treatment prior to surgery. BENGAL implants are used to facilitate fusion in the cervical spine (C2-T1) and are placed via an anterior approach using autogenous bone. When used as an interbody fusion device, DePuy Spine supplemental fixation should be used.

The BENGAL System is indicated for use in the thoracolumbar spine (i.e., T1-L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. This system is also indicated for treating fractures of the thoracic and lumbar spine. This system is designed to restore the biomechanical integrity of the

anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. When used as a vertebral body replacement device this system is intended for use with DePuy Spine supplemental internal fixation.

OCELOT® Stackable Cage System:

510(k) submission K001340 cleared July 26, 2000.

K001340

The Stackable Cage System is indicated for use in the thoracolumbar spine (i.e., T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body.

The Stackable Cage System is also indicated for treating fractures of the thoracic and lumbar spine.

The Stackable Cage System is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period.

The Stackable Cage System is intended for use with supplemental internal fixation. The supplemental internal fixation systems that may be used with the Stackable Cage System include DePuy AcroMed titanium plate or rod systems (e.g. Kaneda SR, University Plate, M-2, ISOLA, VSP, Moss Miami, TiMX, Profile).

G. Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use.

Addition of sterile configuration to previously cleared non-sterile implants now provides these devices as sterile. The subject devices are identical to the predicate devices (K073649, K081917, K052746, K110694, K030833, K082128, K122896, K110454, K023835, and K001340) except that the subject devices will be terminally sterilized via gamma radiation. The design, materials, indications, and technology remain identical to the predicate systems.

H. Materials

The materials of the subject implants remain unchanged from that of the previously cleared implants. The intervertebral body fixation devices are manufactured from Carbon Fiber Filled PEEK-OPTIME LT1 Compound (CFRP), ASTM F-136 implant grade titanium alloy and ASTM 560 tantalum.

I. Performance Data

Performance data is not provided in this submission.

J. Conclusion

The Substantial Equivalence Justification demonstrates that the subject devices are as safe, as effective, and perform as well as the predicate devices.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 13, 2014

Medos International, Srl
% Ms. Linda Bernier
DePuy Synthes Spine, Incorporated
325 Paramount Drive
Raynham, MA 02767

Re: K140759

Trade/Device Name: Bengal System®, Bengal® Stackable System, Devex® System,
Ocelot® Stackable Cage System, Concorde® (Bullet and Inline)
Lumbar Interbody System, Cougar® System, Cougar® LS Lateral
Cage System, Leopard® System

Regulation Number: 21 CFR 888.3080

Regulation Name: Intervertebral body fusion device

Regulatory Class: Class II

Product Code: MAX, ODP, MQP

Dated: May 15, 2014

Received: May 16, 2014

Dear Ms. Bernier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K140759

Device Name

BENGAL® System, CONCORDE® Bullet Lumbar Interbody System, CONCORDE® Inline Lumbar Interbody System, COUGAR® System, DEVEX® System, LEOPARD® System

Indications for Use (Describe)

CONCORDE, COUGAR, DEVEX, and LEOPARD Systems Indications.

The CONCORDE, COUGAR, DEVEX, and LEOPARD Systems are indicated for use as intervertebral body fusion devices in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1). Patients should have six months of non-operative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine and are placed via either a PLIF (CONCORDE), TLIF (CONCORDE, DEVEX, LEOPARD) or anterior (COUGAR) approach using autogenous bone. When used as interbody fusion devices these implants are intended for use with DePuy Spine supplemental internal fixation.

The CONCORDE, COUGAR, DEVEX, and LEOPARD Systems are indicated for use in the thoracolumbar spine (i.e., T1-L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. These systems are also indicated for treating fractures of the thoracic and lumbar spine. These systems are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. When used as a vertebral body replacement device these systems are intended for use with DePuy Spine supplemental internal fixation.

BENGAL System Indications The BENGAL System is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one level of the cervical spine with accompanying radicular symptoms. Patients should have six weeks of non-operative treatment prior to surgery. BENGAL implants are used to facilitate fusion in the cervical spine (C2-T1) and are placed via an anterior approach using autogenous bone. When used as an interbody fusion device, DePuy Spine supplemental fixation should be used.

The BENGAL System is indicated for use in the thoracolumbar spine (i.e., T1-L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. This system is also indicated for treating fractures of the thoracic and lumbar spine. This system is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. When used as a vertebral body replacement device this system is intended for use with DePuy Spine supplemental internal fixation.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Division of Orthopedic Devices

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Indications for Use

510(k) Number (if known)

K140759

Device Name

CONCORDE® Inline Lumbar Interbody System

Indications for Use (Describe)

The CONCORDE, CONCORDE Bullet, CONCORDE Curve, COUGAR, DEVEX, and LEOPARD Systems are indicated for use as intervertebral body fusion devices in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L-2-S1). Patients should have six months of non-operative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine and are placed via either a PLIF (CONCORDE, CONCORDE Bullet), TLIF (CONCORDE, CONCORDE Bullet, CONCORDE Curve, DEVEX, LEOPARD) or anterior (COUGAR) approach using autogenous bone. When used as interbody fusion devices these implants are intended for use with DePuy Spine supplemental internal fixation products.

The CONCORDE, CONCORDE Bullet, CONCORDE Curve, COUGAR, DEVEX, and LEOPARD Systems are indicated for use in the thoracolumbar spine (i.e., T1-L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. These systems are also indicated for treating fractures of the thoracic and lumbar spine. These systems are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. When used as a vertebral body replacement device these systems are intended for use with DePuy Spine supplemental internal fixation products.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

510(k) Number (if known)

K140759

Device Name

COUGAR® LS Lateral Cage System

Indications for Use (Describe)

The COUGAR LS Lateral Cage System is indicated for use in the thoracolumbar spine (i.e., T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. This system is also indicated for treating fractures of the thoracic and lumbar spine. The system is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. When used as a vertebral body replacement device, this system is intended for use with DePuy Spine supplemental internal fixation.

The COUGAR LS Lateral Cage System is also indicated for intervertebral body fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive lateral approach. When used as an interbody fusion device, this system is intended for use with DePuy Spine supplemental internal fixation.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

510(k) Number (if known)

K140759

Device Name

COUGAR® LS Lateral Cage System

Indications for Use (Describe)

The Lateral Cage System is indicated for intervertebral body fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive lateral approach. The Lateral Cage System is intended for use with DePuy Spine supplemental fixation.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

510(k) Number (if known)

K140759

Device Name

BENGAL® Stackable System

Indications for Use (Describe)

The VBR Spinal System is indicated for use in the thoracolumbar spine (i.e., T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body.

The VBR Spinal Systems are also indicated for treating fractures of the thoracic and lumbar spine.

The VBR Spinal Systems are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period.

The VBR Spinal System is intended for use with supplemental internal fixation.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

510(k) Number (if known)

K140759

Device Name

CONCORDE® Bullet Lumbar Interbody System

Indications for Use (Describe)

The Concorde VBR Spinal System is indicated for use in the thoracolumbar spine (i.e., T1-L5) to replace diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body.

The Concorde VBR Spinal System is also indicated for treating fractures of the thoracic and lumbar spine.

The Concorde VBR Spinal System is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period.

The Concorde VBR Spinal System is intended for use with supplemental internal fixation. The supplemental internal fixation systems that may be used with the Concorde VBR Spinal System include DePuy Spine titanium plate or rod systems (i.e., Kaneda SR, University Plate, M-2, ISOIA, VSP, Moss Miami, T MX, MONARCH, Expedium, Viper, and Profile).

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

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Indications for Use

510(k) Number (if known)

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Device Name

COUGAR® System

Indications for Use (Describe)

The DePuy AcroMed VBR System is indicated for use in the thoracolumbar spine (i.e., T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body.

The DePuy AcroMed VBR System is also indicated for treating fractures of the thoracic and lumbar spine.

The DePuy AcroMed VBR System is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period.

The DePuy AcroMed VBR System is intended for use with supplemental internal fixation. The supplemental internal fixation systems that may be used with the VBR System include DePuy AcroMed titanium plate or rod systems (i.e., Kaneda SR, University Plate, M-2, ISOLA, VSP, Moss Miami, TiMX, Monarch, and Profile).

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

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Indications for Use

510(k) Number (if known)
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Device Name
DEVEX® System

Indications for Use (Describe)

The Devex Mesh System is indicated for use in the thoracolumbar spine (T1-L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body.

The Devex Mesh System is also indicated for treating fractures of the thoracic and lumbar spine.

The Devex Mesh System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period.

The Devex Mesh System is intended for use with supplemental internal fixation. The supplemental internal fixation systems that may be used with the Surgical Titanium Mesh System include DePuy AcroMed titanium plate or rod systems (e.g. Kaneda SR, University Plate, M-2, ISOLA, VSP, Moss Miami, TiMX, Monarch and Profile).

Type of Use (Select one or both, as applicable)

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Indications for Use

510(k) Number (if known)

K140759

Device Name

OCELOT® Stackable Cage System

Indications for Use (Describe)

The Stackable Cage System is indicated for use in the thoracolumbar spine (i.e., T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body.

The Stackable Cage System is also indicated for treating fractures of the thoracic and lumbar spine.

The Stackable Cage System is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period.

The Stackable Cage System is intended for use with supplemental internal fixation. The supplemental internal fixation systems that may be used with the Stackable Cage System include DePuy AcroMed titanium plate or rod systems (e.g. Kaneda SR, University Plate, M-2, ISOI.A, VSP, Moss Miami, TIMX, Profile).

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

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